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| APPLICATION NO.  | FILING DATE  | FIRST NAMED INVENTOR   | ATTORNEY DOCKET NO. | CONFIRMATION NO. |          |                       |          |              |      |  |
|--|--------------|--|---------------------|------------------|----------|-----------------------|----------|--------------|------|--|
| 10/814,850   | 03/31/2004   | Govindan Rajamohan   | U 015118-6          | 5613             |          |                       |          |              |      |  |
| 7590<br>LADAS & PARRY<br>26 West 61st Street<br>New York, NY 10023 |              | <table border="1"><tr><td>EXAMINER</td></tr><tr><td>WALICKA, MALGORZATA A</td></tr><tr><td>ART UNIT</td><td>PAPER NUMBER</td></tr><tr><td colspan="2">1652</td></tr></table> |                     |                  | EXAMINER | WALICKA, MALGORZATA A | ART UNIT | PAPER NUMBER | 1652 |  |
| EXAMINER   |              |  |                     |                  |          |                       |          |              |      |  |
| WALICKA, MALGORZATA A  |              |  |                     |                  |          |                       |          |              |      |  |
| ART UNIT   | PAPER NUMBER |  |                     |                  |          |                       |          |              |      |  |
| 1652   |              |  |                     |                  |          |                       |          |              |      |  |
| SHORTENED STATUTORY PERIOD OF RESPONSE                             | MAIL DATE    | DELIVERY MODE  |                     |                  |          |                       |          |              |      |  |
| 3 MONTHS   | 01/30/2007   | PAPER  |                     |                  |          |                       |          |              |      |  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/814,850             | RAJAMOHAN ET AL.    |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Malgorzata A. Walicka  | 1652                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 26 October 2005.
- 2a) This action is **FINAL**.                                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 3 and 10-25 is/are withdrawn from consideration.
- 5) Claim(s) 1 and 2 is/are allowed.
- 6) Claim(s) 4-9 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 31 March 2004 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_

Response to restriction requirement filed Oct. 27, 2006 is acknowledged. Claims 1-25 are pending in the application. Claims 1-2, and 4-9 of group I elected without traverse are under examination.

### **DETAILED ACTION**

#### **Priority**

Applicants claim of benefits of provisional application 60/459,439 filed 04/01/2003 and has been noted. The priority of the instant claims to these applications has been granted.

#### **Objections**

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors in the specification of which applicant may become aware.

Claims 4-6 are objected to because their language should indicate that they are contained in E. coli: "The plasmid ... contained in E. coli Deposit #". Please note that the deposit No. referred to in claims 4-6 are that of E. coli of claims 7-9. The plasmids cannot be deposited only organisms.

#### **Rejections**

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 1 and 2 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. In the absence of the hand of man, naturally occurring proteins and/or nucleic acids are considered non-statutory subject matter; Diamond v. Chakrabaty, 206 USPQ 193 (1980). This rejection may be overcome by amending the claims to contain wording such as "An isolated and purified protein or nucleic acid". It should be noted that a recombinant enzymes/proteins are assumed to be identical to those produced naturally unless otherwise indicated.

### **35 USC 112 first paragraph**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable any person skilled in

the art to which it pertains, or with which it is most nearly connected, to make and use the claimed invention.

The invention appears to employ novel plasmids and *E. coli* cells transformed with them. Since the plasmids are essential to the claimed invention, they must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The claimed plasmids' sequences are not fully disclosed, nor have all the sequences required for their construction been shown to be publicly known and freely available. The transformed *E. coli* cells are not fully disclosed because the plasmids are not fully disclosed. The enablement requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the *E. coli* cells containing the plasmids. The specification does not disclose a repeatable process to obtain the vectors and it is not apparent if the DNA sequences are readily available to the public. Accordingly, it is deemed that a deposit of these plasmids should have been made in accordance with 37 CFR 1.801-1.809.

It is noted that applicants have deposited the organisms but there is no indication in the specification as to public availability. If the deposit was made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be available to the public under the conditions specified in 37 CFR 1.808, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide

assurance or compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

1. during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
2. upon granting of the patent the strain will be available to the public under the conditions specified in 37 CFR 1.808;
3. the deposit will be maintained in a public repository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and
4. the deposit will be replaced if it should ever become inviable.

### **Conclusion**

Claims 1-9 are rejected but contain allowable subject matter. Applicants disclosed DNA molecule of SEQ ID NO: 1 which assures high expression of Staphylococcal kinase in *E. coli*. Applicants also disclose a new modified staphylokinase gene of SEQ ID NO: 2 that may be successfully expressed in *E. coli*. The unmodified staphylococcal kinase has been thus far difficult to express in *E. coli*, which prevented an efficient recombinant production of the enzyme. The enzyme has utility in clinics in trombolytic treatment. The art does not disclose or suggest SEQ ID NO: 1 and SEQ ID NO: 2.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka whose telephone number is (571) 272-0944. The examiner can normally be reached on Monday-Friday from 10:00 a.m. to 4:30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Malgorzata A. Walicka, Ph.D.

Art Unit 1652

Patent Examiner



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